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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,178	08/09/2001	Vladimir Bakhutashvili	#627-A	6379

7590 05/06/2003  
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EXAMINER

DAVIS, RUTH A

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 05/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/928,178

Applicant(s)

BAKHUTASHVILI, VLADIMIR

Examiner

Ruth A. Davis

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 85-88 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 85-88 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Applicant's amendment filed February 24, 2003 has been received and entered into the case. Claims 1 – 10 and 83 – 84 have been canceled; claims 85 – 88 have been added. Claims 85 – 88 are pending and have been considered on the merits. All arguments have been fully considered.

#### ***Claim Objections***

1. Claim objections have been withdrawn due to amendment.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 86 and 88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 86 and 88 are drawn to a method for protecting against effects of TNF, however are rendered vague and indefinite for reciting "at least one characteristic peak" because it is unclear if applicant intends to claim any compound that has any peak in either figure 2 or 3. Moreover, it is unclear what compositions are encompassed by this limitation. For example, is any composition that has any of the peaks in figures 2 and/or 3 suitable for the method?

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Claims 85 – 88 have been interpreted as administering compositions of plaferon LB and/or fractions of plaferon LB, as figures 2 and 3 are disclosed to be chromatography results of these compounds.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 85 – 88 are rejected under 35 U.S.C. 102(b) as being anticipated by Kokaia et al. (1996).

Applicant claims methods for protecting against effects of TNF in cells or subjects, wherein the cells or subjects are contacted/administered an effective amount of a composition with apoptosis modulating activity obtained from amniotic tissue, and has characteristic peaks as set forth in Figures 2 or 3. The composition may alternatively have at least one of the characteristic peaks of figures 2 or 3.

Kokaia teaches administration of plaferon LB to subjects.

Although the reference does not specifically teach the “characteristic peaks” as set forth in figures 2 and/or 3, the compositions appear to be the same. In addition, although the reference does not specifically teach the method for protecting against effects of TNF,

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the method steps are the same. Moreover, by practicing the methods of Kokaia, one in the art would inherently be protecting against effects of TNF, as such properties are intrinsic to the plaferon LB composition.

Therefore, the reference anticipates the claimed subject matter.

6. Claims 85 – 88 are rejected under 35 U.S.C. 102(a) as being anticipated by Pantsulaya et al (Proc. Georgian Acad Sci Biol. Ser, 1999).

Applicant claims methods for protecting against effects of TNF in cells or subjects, wherein the cells or subjects are contacted/administered an effective amount of a composition with apoptosis modulating activity obtained from amniotic tissue, and has characteristic peaks as set forth in Figures 2 or 3. The composition may alternatively have at least one of the characteristic peaks of figures 2 or 3.

Pantsulaya teaches contacting plaferon LB and fractions thereof to cells wherein immuno-modulatory activity was shown (p.75).

Although the reference does not specifically teach the “characteristic peaks” as set forth in figures 2 and/or 3, the reference does provide peak data which appear to exhibit peaks as claimed. In addition, the compositions appear to be the same. Further, although the reference does not specifically teach the method for protecting against effects of TNF, the method steps are the same. Moreover, by practicing the methods of Pantsulaya, one in the art would inherently be protecting against effects of TNF, as such properties are intrinsic to the plaferon LB composition.

Therefore, the reference anticipates the claimed subject matter.

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7. Claims 85 – 88 are rejected under 35 U.S.C. 102(a) as being anticipated by Bakhutashvili et al. (1999).

Applicant claims methods for protecting against effects of TNF in cells or subjects, wherein the cells or subjects are contacted/administered an effective amount of a composition with apoptosis modulating activity obtained from amniotic tissue, and has characteristic peaks as set forth in Figures 2 or 3. The composition may alternatively have at least one of the characteristic peaks of figures 2 or 3.

Bakhutashvili teaches administering plaferon LB to subjects wherein protective effects occurred (p.975-976).

Although the reference does not specifically teach the “characteristic peaks” as set forth in figures 2 and/or 3, the compositions appear to be the same. In addition, although the reference does not specifically teach the method for protecting against effects of TNF, the method steps are the same. Moreover, by practicing the methods of Bakhutashvili, one in the art would inherently be protecting against effects of TNF, as such properties are intrinsic to the plaferon LB composition.

Therefore, the reference anticipates the claimed subject matter.

8. Claims 85 – 88 are rejected under 35 U.S.C. 102(b) as being anticipated by Bakhutashvili et al. (J heart Failure, Vol.4, No.1, 1997).

Applicant claims methods for protecting against effects of TNF in cells or subjects, wherein the cells or subjects are contacted/administered an effective amount of a composition with apoptosis modulating activity obtained from amniotic tissue, and has

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characteristic peaks as set forth in Figures 2 or 3. The composition may alternatively have at least one of the characteristic peaks of figures 2 or 3.

Bakhutashvili teaches administering plaferon LB to subjects wherein protective effects occurred (p.151).

Although the reference does not specifically teach the “characteristic peaks” as set forth in figures 2 and/or 3, the compositions appear to be the same. In addition, although the reference does not specifically teach the method for protecting against effects of TNF, the method steps are the same. Moreover, by practicing the methods of Bakhutashvili, one in the art would inherently be protecting against effects of TNF, as such properties are intrinsic to the plaferon LB composition.

Therefore, the reference anticipates the claimed subject matter.

9. Claims 85 – 88 are rejected under 35 U.S.C. 102(b) as being anticipated by Bakhutashvili et al. (The Immunologist, Nov 1998).

Applicant claims methods for protecting against effects of TNF in cells or subjects, wherein the cells or subjects are contacted/administered an effective amount of a composition with apoptosis modulating activity obtained from amniotic tissue, and has characteristic peaks as set forth in Figures 2 or 3. The composition may alternatively have at least one of the characteristic peaks of figures 2 or 3.

Bakhutashvili teaches administering plaferon LB to subjects wherein protective effects against growth factors, inflammation and oxidation occurred (abstract).

Although the reference does not specifically teach the “characteristic peaks” as set forth in figures 2 and/or 3, the compositions appear to be the same. In addition, although

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the reference does not specifically teach the method for protecting against effects of TNF, the method steps are the same. Moreover, by practicing the methods of Bakhutashvili, one in the art would inherently be protecting against effects of TNF, as such properties are intrinsic to the plaferon LB composition.

Therefore, the reference anticipates the claimed subject matter.

### ***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310.

The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad  
May 2, 2003



LEON B. LANKFORD, JR.  
PRIMARY EXAMINER